

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kameswari S. Konduri, et al
Serial No.: 10/769,034
Filed: 01/30/04
TC: 1633
Examiner: Kevin K. Hill

For: A Sterically Stabilized Carrier for Aerosol
Therapeutics, Compositions and Methods For
Treating Diseases of the Respiratory Tract of a Mammal

MS Board of Patent Appeals and Interferences
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REVISIONS PURSUANT TO NOTIFICATION
OF NON-COMPLIANT APPEAL BRIEF

Response to a Notification of Non-Compliant Appeal Brief mailed October 25, 2007,
attached hereto are revised pages to bring the Appeal Brief into compliance. Per a telephone
communication with Darlene Brown, Patent Appeal Center Specialist, only the revised pages are
being forwarded.

Respectfully submitted,

F. Lindsey Scott
F. Lindsey Scott
Attorney for the Applicant

REAL PARTY IN INTEREST

This Application is assigned to VGSK Technologies, Inc., the real party in interest, by an assignment recorded April 11, 2006 at Reel/Frame 017856/0582.

RELATED APPEALS AND INTERFERENCES

None.

STATUS OF CLAIMS

Applicants' claims 1-5, 8-13, 16-19, 22-29, 32-38, 41-45, 48-49 and 52 (using Examiner's required renumbering) were rejected by the Examiner in the Office Action mailed March 1, 2007.

The present status of the claims as stated in the Office Action mailed March 1, 2007 is:

Pending: 1-6, 8-19, 22-30, 33-39, 42-50, 52 and 53.

Objected to: 4, 13 and 45.

Withdrawn: 6, 14, 15, 28, 30-32, 46 and 47.

Previously cancelled: 7, 20-21, 31-32, 40-41 and 51.

The claim status above represents the status of the claims prior to the un-entered amendment after final filed July 19, 2007.

Claim 53 was considered by the Examiner to be pending but was not addressed by the Examiner in the Office Action summary Mailed March 1, 2007. This claim has been assumed to be rejected.

The claims under appeal are claims 1-5, 8-13, 16-19, 22-29, 32-38, 41-45, 48-49 and 52-53. These claims presently stand finally rejected. A clean copy of these claims is attached

An amendment mailed July 19, 2007, reflecting amendments to the claims, has been denied entry.

In the compilation of the Status of the Claims above, certain inconsistencies have been noticed in the Office Action Summary mailed March 1, 2007 and the Examiner's comments under the heading "Amendments" in the Detailed Action attached thereto. As a result, there are some double entries in the listing of the status of the claims. It is concluded that the claims under appeal are as shown above.

STATUS OF AMENDMENTS

The subject application was filed initially as U.S. Serial No. 10/769,034 on January 30, 2004 by Kameswari S. Konduri, Sandhya Nandedkar, Nejat Duzgunes, Pattisapu Ram Jogi Gangadharma

duplicate Applicants' claimed invention. Among other arguments made by the Examiner in this Office Action was the argument that "The drug carried by the liposome is immaterial to the enablement rejection." This statement was made after the restriction requirement to a single drug was required by the Examiner. Various other arguments were raised with respect to support in the application for various claims and additional rejections under 35 U.S.C. 112 were made.

Rejections were made under 35 U.S.C. 102 over Onyuksel.

Rejections were made under 35 U.S.C. 103 over Onyuksel, Waldrep and Konduri, et al.

A response to this Office Action was mailed to the Patent Office July 19, 2007 with a request for a two-month extension of time to file. This response was not entered.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention is a carrier comprising phosphatidylglycerol, phosphatidylcholine, and poly(ethylene glycol) adapted to encapsulate a drug for aerosol administration to the lungs of a mammal. The formulation comprising the carrier and the drug provide extended effective life for the drug in the lungs of a mammal. The invention is claimed as a carrier formulation in claim 1 and is supported by the specification at page 3, line 20 through page 4, line 2; page 7, line 15 through page 8, line 15; page 10, line 5 and the examples, a composition comprising the carrier and an encapsulated drug in claim 18 as supported by the specification at page 4, lines 2-7; page 7, line 15 through page 8, line 15; page 10, line 5 and the examples, a method in claim 34 for treating the lungs of a mammal using the combined drug and carrier as supported by the specification at page 3, lines 8-13 page 7, line 15 through page 8, line 15; page 10, line 5 and the examples.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Is Applicants' spelling and hyphenation of chemical compounds correct? This issue, first raised in the final rejection, has been addressed in the amendment filed July 19, 2007, which was refused entry. Applicants are willing to make the required changes as submitted in the amendment after final.

Claims Appendix

1. A sterically stabilized liposome carrier wherein the carrier contains phosphatidylcholine, phosphatidylglycerol and poly(ethylene glycol), the carrier encapsulating budesonide for aerosol administration, the carrier being compatible with a respiratory tract of a mammal and effective to extend the effective life of the budesonide in the respiratory tract by a time equal to at least twice the effective life of the budesonide alone.
2. The carrier of claim 1 wherein the time is equal to at least three times the effective life of the budesonide alone.
3. The carrier of claim 1 wherein the carrier contains phosphatidylcholine in an amount up to 99% of the total phosphatidylcholine and phosphatidylglycerol in the carrier.
4. The carrier of claim 3 wherein the carrier further comprises phosphatidylglycerol.
5. The carrier of claim 1 wherein the drug comprises budesonide.
8. The carrier of claim 1 wherein the poly(ethylene glycol) has a molecular weight from about 500 to about 5,000 daltons.
9. The carrier of claim 1 wherein poly(ethylene glycol) is attached to lipids such as cholesterol or phosphatidylethanolamine having acyl chains containing from about 8 to about 18 carbon atoms.
10. The carrier of claim 9 wherein the acyl chains contain from about 16 to about 18 carbon atoms.
11. The carrier of claim 9 wherein the acyl groups comprise at least one of distearoyl, stearoyl oleoyl, oleoyl stearoyl, stearoyl palmitoyl, dipalmitoyl, dioleoyl, palmitoyl oleoyl and dipalmitoleoyl.

12. The carrier of claim 1 wherein the carrier comprises at least one of poly(ethylene glycol) conjugated lipids, phosphatidylinositol, dipalmitoylphosphatidylpolyglycerol, lipid conjugated polyoxyethylene, lipid conjugated polysorbate, or lipids conjugated to other hydrophilic steric coating molecules safe for in vivo use, the sterically stabilized liposome being effective to extend the effective lifetime of the budesonide in the respiratory tract of a mammal.

13. The carrier of claim 1 wherein the carrier contains phosphatidylcholine and phosphatidylglycerol, poly(ethylene glycol) distearylphosphatidyl diethanolamine, with or without cholesterol.

16. The carrier of claim 1 wherein the carrier comprises egg-derived or soybean-derived phosphatidylcholine.

17. The carrier of claim 1 wherein the carrier comprises egg-derived or soybean-derived phosphatidylglycerol.

18. A composition comprising a sterically stabilized liposome carrier wherein the carrier contains phosphatidylcholine, phosphatidylglycerol and poly(ethylene glycol) encapsulating budesonide, the composition being compatible with a respiratory tract of a mammal, aerosol administration and effective to extend the effective life of the budesonide in the respiratory tract by a time equal to at least twice the effective life of the budesonide alone.

19. The composition of claim 18 wherein the time is equal to at least three times the effective life of the budesonide alone.

22. The composition of claim 18 wherein the phosphatidylcholine is present in an amount equal to from about 50 to about 100 weight percent.

23. The composition of claim 21 wherein the carrier comprises up to about 50

weight percent phosphatidylglycerol.

24. The composition of claim 20 wherein the carrier further comprises poly(ethylene glycol).

25. The composition of claim 24 wherein the poly(ethylene glycol) has a molecular weight from about 500 to about 5,000 Daltons.

26. The composition of claim 18 wherein at least one of phosphatidylcholine, phosphatidylglycerol or poly(ethylene glycol)-derivatized lipid have acyl chains containing from about 8 to about 18 carbon atoms.

27. The composition of claim 26 wherein the acyl groups comprise at least one of distearoyl, stearoyl oleoyl, oleoyl stearoyl, stearoyl palmitoyl, dipalmitoyl, dioleoyl, palmitoyl oleoyl and dipalmitoleoyl.

28. The composition of claim 18 wherein the carrier comprises at least one of poly(ethylene glycol) conjugated lipids, phosphatidylinositol, dipalmitoylphosphatidylpolyglycerol, lipid conjugated polyoxyethylene, lipid conjugated polysorbate, or lipids conjugated other hydrophilic steric coating molecules safe for in vivo use, the sterically stabilized liposome being effective to extend the effective lifetime of budesonide in the respiratory tract of a mammal.

29. The composition of claim 18 wherein the carrier contains phosphatidylcholine, phosphatidylglycerol, and poly(ethylene glycol) distearylphosphatidyl diethanolamine.

32. The composition of claim 18 wherein the carrier comprises egg-derived or soybean-derived phosphatidylcholine.

33. The composition of claim 18 wherein the carrier comprises egg-derived or

soybean-derived phosphatidylglycerol.

34. A method for treating the respiratory tract of a mammal by aerosol administration of an effective amount of a composition comprising a sterically stabilized liposome carrier wherein the carrier contains phosphatidylcholine, phosphatidylglycerol and poly(ethylene glycol) with the carrier encapsulating budesonide, the sterically stabilized liposome being compatible with the respiratory tract of a mammal and effective to extend the effective life of the budesonide in the respiratory tract by a time equal to at least twice the effective life of the budesonide alone.

35. The method of claim 34 wherein the carrier comprises phosphatidylcholine and wherein at least 50 percent of the head groups contain phosphatidylcholine.

36. The method of claim 35 wherein the carrier further comprises phosphatidylglycerol.

37. The method of claim 35 wherein the phosphatidylcholine is present in an amount equal to from about 50 to about 100 weight percent.

38. The carrier of claim 36 wherein the carrier comprises up to about 50 weight percent phosphatidylglycerol.

41. The method of claim 34 wherein the poly(ethylene glycol) is attached to a lipid such as phosphatidylethanolamine and has acyl chains containing from about 8 to about 18 carbon atoms.

42. The method of claim 41 wherein the acyl chains contain from about 16 to about 18 carbon atoms.

43. The method of claim 41 wherein the acyl groups comprise at least one of distearoyl, stearoyl oleoyl, oleoyl stearoyl, stearoyl palmitoyl, dipalmitoyl, dioleoyl, palmitoyl

oleoyl and dipalmitoleoyl.

44. The method of claim 34 wherein the carrier comprises at least one of poly(ethylene glycol) conjugated lipids, phosphatidylinositol, dipalmitoylphosphatidylpolyglycerol, lipid conjugated polyoxyethylene, lipid conjugated polysorbate, or lipids conjugated other hydrophilic steric coating molecules safe for in vivo use, the sterically stabilized liposome being effective to extend the effective lifetime of a drug in the respiratory tract of a mammal.

45. The method of claim 34 wherein the carrier contains phosphatidylcholine, phosphatidylglycerol, and poly(ethylene glycol) distearylphosphatidyl diethanolamine, with or without cholesterol.

48. The method of claim 34 wherein the carrier contains egg-derived or soybean-derived phosphatidylglycerol.

49. The method of claim 34 wherein the carrier contains egg-derived or soybean-derived phosphatidylglycerol.

52. The carrier of claim 1 wherein the carrier contains distearylphosphatidyl diethanolamine-cholesterol.

53. The carrier of claim 1 wherein the carrier contains distearylphosphatidylethanolamine-cholesterol.